

REMARKS

Claims 1-7 have been amended. Claims 8-38 were canceled, and claim 39 has been withdrawn as being directed to a non-elected invention. Claims 40-41 have been added. Therefore, claims 1-7 and 40-41 are pending in the captioned application. Entrance of the amendments and further examination and reconsideration of claims 1-7 and 40-41 are respectfully requested.

Priority Claim Under 35 U.S.C. 119(e)

The Office Action states that "Priority to provisional US application 60/153,941 remains denied for the reasons stated in the previous Office Action." (Office Action -- page 2.) Applicant respectfully traverses this assertion. Adequate support for the present claims is provided in U.S. Provisional Application Serial No. 60/153,941 (hereinafter "the Provisional Application").

For example, the Provisional Application states that "[n]one of the prior art references disclose methods which achieve the goals of the present invention, that of using the analysis of 200-300 biochemicals in a single sample of blood." (Provisional Application -- page 2, lines 5-7.) In addition, the Provisional Application states that an electronic database includes "a first set of information derived from a multiplexed analysis of a biological sample of an individual against a Multi-Analyte Profile (MAP) comprising a plurality of predetermined analytes." (Provisional Application -- page 2, lines 10-12.) The Provisional Application further states that "The MAP includes 50 or more, 100 or more, 200 or more, or 300 or more separate analytes. The first set of information includes quantitative information for each analyte of said MAP which is found in the biological sample." (Provisional Application -- page 2, lines 14-17.) The Provisional Application also states:

Currently, the level of biochemical screening proposed for this project can only be performed by technology developed by Luminex and disclosed as published patent applications: Microparticles with Multiple Fluorescent Signals, WO99/37814; Multiplexed Analysis of Clinical Specimens Apparatus and Methods, WO99/36564; Interlaced Lasers for Multiple Fluorescence Measurement, WO98/59233; and Precision Fluorescently Dyed Particles and Methods of Making and Using Same, WO99/19515. This technology allows the simultaneous determination of the concentrations of multiple biochemicals in a single sample of blood or other biological fluids. In this application, this technology will be referred to as the 'Luminex' technology and the profile of concentrations of biochemicals derived is referred to as a Multi-Analyte Profile (MAP). (Provisional Application -- page 5, lines 14-23.)

Furthermore, the Provisional Application states:

This simple low-cost procedure delivers sophisticated diagnostic information. A test of an individual's blood includes a 200-300 analyte MAP, and comparative analysis of patient results with the Luminex Project database. Profiling becomes an essential part of the routine annual check-up, offering all the common screening tests plus substantially more diagnostic information obtained by testing for hundreds of additional analytes and checking the results against the database. (Provisional Application -- page 9, lines 6-12.)

The Provisional Application further states:

The ability to discern clinically relevant biochemical changes in the blood or other biological fluids is useful in other ways besides diagnosing disease. The extensive testing for safety and efficacy now required of pharmaceutical companies before the introduction of a new drug is covered by MAP studies. In the testing methods employed today, the biochemical alterations of a relatively few biochemical markers are studied. Side effects of drugs are detected by alterations in the hundreds of analytes in the database. The drug developer detects such side effects with a simple clinical trial of 500 people, tested monthly for two years. (Provisional Application -- page 11, lines 8-15.)

In addition, the Provisional Application states that "said first set of information includes quantitative information for each analyte of said MAP which is found in the biological sample." (Provisional Application -- page 13, lines 10-12.)

As such, Applicant believes that the Provisional Application provides sufficient support for the present claims. Accordingly, Applicant respectfully requests that the denial of priority to the Provisional Application be withdrawn.

Double Patenting Rejections

Claims 1-7 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 7, and 8 of U.S. Patent No. 6,524,793 to Chandler et al. in view of International Publication No. WO 99/19515 to Chandler et al. (hereinafter "the International Publication"). Applicant respectfully traverses these rejections. However, to expedite prosecution, a Terminal Disclaimer is submitted in separate paper to obviate the double patenting rejections in accordance with 37 C.F.R. § 1.321(c). The Terminal Disclaimer is believed sufficient to overcome any assertion of judicially created obviousness-type double patenting between the present claims

and claims of U.S. Patent No. 6,524,793 to Chandler et al. Accordingly, removal of the double patenting rejections of claims 1-7 is respectfully requested.

Section 112, second paragraph, Rejections

Claims 1-7 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant sincerely appreciates the Examiner's detailed explanation of the § 112, second paragraph, rejections provided on page 4 of the Office Action. Claims 1, 2, and 7 have been amended to address the specific problems in these claims identified in the Office Action.

The Office Action states that "[c]laim 5 recites 'natural product.' It is unclear what limitation is intended by 'natural product,' as this could include any known natural product. Clarification is requested." (Office Action — page 4.) Amended claim 5 recites in part: "wherein the at least one reagent comprises a small molecule, natural product, synthetic polymer, peptide, polypeptide, polysaccharide, lipid, nucleic acid, or combinations thereof." Amended claim 1, from which claim 5 depends, recites in part: "at least one reagent designed to interact selectively with a predetermined analyte." Therefore, a "natural product" as recited in claim 5 is defined in the claims as a natural product that is designed to interact selectively with a predetermined analyte. Therefore, the claimed natural product does not include any known natural product as suggested in the Office Action. Instead, the claimed natural product includes only those natural products that are designed to interact selectively with a predetermined analyte. It is well within the skill of one of ordinary skill in the art to determine if a natural product is designed to interact selectively with a predetermined analyte. For example, one of ordinary skill in the art would be able to determine if a "natural product" is designed to interact selectively with a predetermined analyte such as one of those recited in claim 6. As such, Applicant believes that the recitation of the term "natural product" in claim 5 does not render claim 5 indefinite.

For at least the reasons set forth above, amended claims 1-7 are believed to be definite since these claims particularly point out and distinctly claim the subject matter which applicant regards as the invention. As such, removal of the § 112, second paragraph, rejections of claims 1-7 is respectfully requested.

Section 103(a) Rejections

Claims 1-7 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kettman et al. (Cytometry (1998) 33:234-243) (hereinafter "Kettman") in view of Ekins (Journal of Pharmaceutical and Biomedical Analysis (1989) Vol. 7, pages 155-168) (hereinafter "Ekins"). As will be set forth in more detail below, the § 103(a) rejections of claims 1-7 are respectfully traversed.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974), MPEP 2143.03. Obviousness cannot be established by combining or modifying the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion or incentive to do so. *In re Bond*, 910 F. 2d 81, 834, 15 USPQ2d 1566, 1568 (Fed. Cir. 1990). The cited art does not teach or suggest all limitations of the currently pending claims, some distinctive limitations of which are set forth in more detail below.

The cited art does not teach or suggest a Multi-Analyte Profile (MAP) Test Panel that includes 75 or more subsets of microspheres. Amended independent claim 1 recites in part: "[a] Multi-Analyte Profile (MAP) Test Panel comprising 75 or more subsets of microspheres." Amended independent claim 7 recites a similar limitation.

Kettman discloses classification and properties of 64 multiplexed microsphere sets. Kettman, however, does not disclose a Multi-Analyte Profile (MAP) Test Panel that includes 75 or more subsets of microspheres. For example, Kettman states that "This measurement system can analyze up to 64 analytes in a single sample." (Kettman -- abstract, col. 1 emphasis added.) Therefore, Kettman does not suggest or provide motivation for testing more than 64 microsphere sets since Kettman discloses that the particular measurement system that was used in the experiments cannot analyze more than 64 analytes in a single sample. As such, Kettman does not teach, suggest, or provide motivation for a Multi-Analyte Profile (MAP) Test Panel that includes 75 or more subsets of microspheres, as recited in claims 1 and 7. Consequently, Kettman does not teach, suggest, or provide motivation for all limitations of claims 1 and 7.

The Office Action also notes that "Kettman et al. do not teach 75, 100, 200, 300 or more subsets of microspheres or 75 analytes in an analysis. However, Ekins teaches a multi-analyte immunoassay in which tens or hundreds of substances can be measured simultaneously (abstract), therefore suggesting

increasing the analyte and microsphere values in order to increase the capability of medical diagnosis and drug design, for example." (Office Action – page 6.)

Although Ekins describes "enabling the simultaneous measurement of tens or even hundreds of substances simultaneously in the same small sample" (Ekins – page 155) as noted in the Office Action, Kettman cannot be combined with Ekins to overcome deficiencies therein. For example, Ekins does not disclose a test panel that includes any microspheres at all. Instead, Ekins describes an assay in which different antibodies are located at different places on one surface which after exposure to a sample is scanned by a laser in a procedure closely resembling the operation of data-storage devices.

For example, Ekins states that "[f]luorescent labels are particularly useful in this context because, by the use of laser scanning techniques, they readily permit arrays of different antibody 'microspots' distributed over a surface, each directed against a different analyte, to be individually examined, thus enabling multiple assays to be simultaneously be carried out on the same small sample." (Ekins – page 166, emphasis added.) In addition, Ekins states that "the technology involved closely resembles that employed in compact disk recorders and other similar data-storage devices, the obvious difference being the light emitted from each of the discrete zones forming the antibody array is fluorescent rather than reflected, and yields chemical rather than physical information." (Ekins – page 167.) Ekins further states that "Clearly the accommodation of a large range of individual immunoassays on a small immunoprobe, comparable in its overall physical dimensions with a few drops of blood, would totally transform the logistics of immunodiagnostic testing." (Ekins -- page 167, emphasis added.)

Therefore, Ekins discloses an entirely different test panel than that of Kettman in that the test panel of Ekins includes one small immunoprobe much like a compact disk or data-storage device (instead of microspheres) on which different analytes are located at different positions. As such, since Ekins does not include any teaching related to a test panel that includes microspheres, Ekins can provide no teaching or suggestion for modifying the test panel of Kettman as suggested in the Office Action. For example, although Ekins teaches simultaneous measurement of tens or hundreds of substances, Ekins does not teach or suggest that such measurements may be performed with any system other than the compact disk recorder-like system described by Ekins. Therefore, Ekins does not teach or suggest using the system of Kettman (a flow cytometer) to perform simultaneous measurements of tens or hundreds of substances. In addition, since Ekins does not include any teaching related or relevant to the system of Kettman, Ekins cannot teach or suggest that the system of Kettman is capable of performing simultaneous measurements of

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tens or hundreds of substances. Furthermore, Kettman discloses that the flow cytometer taught by Kettman is only capable of analyzing up to 64 analytes. Furthermore, since Ekins does not include any teaching related or relevant to the system of Kettman, Ekins cannot provide any suggestion or motivation that the system of Kettman could be modified (or how it could be modified) so that it could be used to analyze more than 64 analytes simultaneously. Therefore, the combination of Ekins and Kettman does not teach or suggest that the system of Kettman can be used to analyze more than 64 analytes simultaneously.

The Office Action also states that "One of ordinary skill in the art would have reasonably expected success in using hundreds of microspheres because Ekins teaches, 'it is both conceivable and within the range of present technology that immunoprobe will be developed capable of measuring every hormone (or iso-hormone component), together with other endocrinologically related substance within a single sample of blood....'" (Office Action -- page 7.) However, the teachings of Ekins cannot suggest to one of ordinary skill in the art to reasonably expect success in using hundreds of microspheres because Ekins does not teach or suggest that these "immunoprobes" are or can be microspheres. Instead, Ekins specifically teaches, as set forth in more detail above, that each immunoprobe includes different analytes located at different locations on one surface resembling that of a compact disk or other data-storage device. As such, since Ekins contains no teaching related to microspheres or tests involving microspheres, Ekins cannot suggest a reasonable expectation of success to one of ordinary skill in the art for using hundreds of microspheres in the tests or systems taught by Ekins.

As such, Kettman, Ekins, and the combination of Kettman and Ekins do not teach, suggest, or provide motivation for a Multi-Analyte Profile (MAP) Test Panel that includes 75 or more subsets of microspheres, as recited in claims 1 and 7. Consequently, the cited art does not teach, suggest, or provide motivation for all limitations of claims 1 and 7.

For at least the reasons stated above, independent claims 1 and 7, as well as claims dependent therefrom, are patentably distinct over the cited art. Accordingly, removal of this rejection is respectfully requested.

Patentability of the Added Claims

The present amendment adds claims 40 and 41. Support for these claims can be found in claim 2 as originally filed. Claims 40 and 41 are dependent from claim 1. Therefore, claims 40 and 41 are patentable over the cited art for at least the reasons set forth above. Accordingly, allowance of claims 40-41 is respectfully requested.

CONCLUSION

This response constitutes a complete response to all issues raised in the Office Action mailed July 6, 2004. In view of the remarks traversing rejections presented therein, Applicants assert that pending claims 1-7 and 40-41 are in condition for allowance. If the Examiner has any questions, comments, or suggestions, the undersigned earnestly requests a telephone conference.

The Commissioner is authorized to charge the any fees, or credit any overpayment, to Conley Rose, P.C. Deposit Account No. 50-3268/5868-02801.

Respectfully submitted,

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